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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,287	10/03/2001	Maria Alexandra Glucksmann	10147-61U1 (MPI2000-471PI	9083

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EXAMINER	
LACOURCIERE, KAREN A	
ART UNIT	**PAPER NUMBER**
1635	8

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/970,287	GLUCKSMANN ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 13-18, drawn to a method of inhibiting the ability of a cell to degrade an extracellular matrix by inhibiting the expression of 22437 gene of SEQ ID NO:1, classified in class 514, subclass 44.

II. Claims 1-7 and 13-18, drawn to a method of inhibiting the ability of a cell to degrade an extracellular matrix by inhibiting the expression of 22437 gene of SEQ ID NO:3, classified in class 514, subclass 44.

III. Claims 1 and 8-18, drawn to a method of inhibiting the ability of a cell to degrade an extracellular matrix by inhibiting 22437 catalytic activities without effecting gene expression, classified in class 514, subclass 2.

IV. Claims 19-25, drawn to a method of assessing a test compound for the ability to modulate tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing by measuring the activity of a 22437 protein, classified in class 435, subclass 6.

V. Claim 26, drawn to a method of making a pharmaceutical composition, classified in class 536, subclass 25.3.

VI. Claim 27, drawn to a method of modulating tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth,

wound healing or cerebral injury healing in a human, classified in class 514, subclass 1.

VII. Claim 28-30, drawn to a method of assessing a test compound for the ability to modulate tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing by measuring the binding of the compound to a 22437 protein encoded by SEQ ID NO:1, classified in class 435, subclass 7.1.

VIII. Claim 28-30, drawn to a method of assessing a test compound for the ability to modulate tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing by measuring the binding of the compound to a 22437 protein encoded by SEQ ID NO:3, classified in class 435, subclass 7.1.

IX. Claim 28-30, drawn to a method of assessing a test compound for the ability to modulate tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing by measuring the binding of the compound to a 22437 protein of SEQ ID NO:2, classified in class 435, subclass 7.1 .

Claims 1-7 and 13-18 link inventions I and II. Claims 1 and 13-18 link inventions I, II and III. Claims 28-30 link inventions VII, VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked

inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 USC 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation in that each of the methods operates by inhibiting the expression of a structurally distinct nucleotide sequence, using antisense sequences which are structurally distinct based on the sequence of the target gene. Each of these methods would require a separate and distinct search based on this structure. A search of more than one (1) of the target sequences claimed in Groups I and II presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of these sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination.

Inventions I and II are unrelated to Invention III. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group I and II use nucleic acids, which are composed of nucleotides, and act by inhibiting the expression of 22437 protein, whereas Group II uses proteins, which are composed of amino acids, and act by inhibiting the activity of 22437 protein directly, without effecting the expression of said protein.

Inventions I and II and III are unrelated to the invention of Group IV. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with completely different method steps and different effects. For example, each of the methods of Groups I and II and III have the effect of inhibiting the ability of a cell to degrade an extracellular matrix, whereas the methods of Group IV have the effect of determining a compound's ability to modulate tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing.

Inventions I and II and III are unrelated to Invention V. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with completely different method steps and different effects. For example, each of the methods of Groups I and II and III have the effect of inhibiting the ability of a cell to degrade an

extracellular matrix, whereas the methods of Group V have the effect of making a pharmaceutical composition.

Inventions I and II and III are unrelated to Invention VI. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with completely different method steps and different effects. For example, each of the methods of Groups I and II and III have the effect of inhibiting the ability of a cell to degrade an extracellular matrix, whereas the methods of Group VI have the effect of modulating tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing in a human

Inventions I and II and III are unrelated to Invention VII and VIII and IX. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with completely different method steps and different effects. For example, each of the methods of Groups I and II and III have the effect of inhibiting the ability of a cell to degrade an extracellular matrix, whereas the methods of Group VII and VIII and IX have the effect of identifying a compound useful for modulating tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different

effects. For example, the methods of Groups IV have the effect of have the effect of assessing a test compound for the ability to modulate tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing, whereas the methods of Group V have the effect of making a pharmaceutical composition.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with completely different method steps and different effects. For example, the methods of Groups IV have the effect of have the effect of assessing a test compound for the ability to modulate tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing, whereas the methods of Group VI have the effect of modulating tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing in a human.

Invention IV is unrelated to each of the Inventions VII and VIII and IX. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods different modes of operation, which results in methods of different steps. For example, the methods of Groups IV operate by assessing the effect of a compound by monitoring the activity of a 22437 protein, whereas each of the methods of Groups VII, VIII and IX operate by assessing a compound by monitoring the binding of the compound to a protein.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04,

MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Groups V have the effect of making a pharmaceutical composition whereas the method of Group VI have the effect of modulating tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing in a human.

Invention V is unrelated to Invention VII and VIII and IX. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group V have the effect of making a pharmaceutical composition, whereas each of the methods of Group VII and VIII and IX have the effect of identifying a compound useful for modulating tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing by determining a compound's ability to bind to a protein.

Invention VI is unrelated to Inventions VII and VIII and IX. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with completely different method steps and different effects. For example, the methods of Group VI have the effect of modulating tumor establishment, growth or metastasis, epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing in a human, whereas each of the methods of Group VII and VIII and IX have the effect of identifying a compound useful for modulating tumor establishment, growth or metastasis,

epithelial or endothelial cell proliferation, neuronal cell growth, wound healing or cerebral injury healing by determining a compound's ability to bind to a protein.

Inventions VII and VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation in that each of the methods assesses the binding of a compound to a structurally different protein (i.e. proteins with a different amino acid sequence, therefore a different structure). Each of these methods operate by assessing binding for a distinct protein and, further, would require a separate and distinct search based on this structure. Each of these methods would require a separate and distinct search based on this structure. A search of more than one (1) of the amino acid sequences used in the methods of in Groups VII and VIII and IX presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of these sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group VII is not required for Group VIII and IX, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
June 22, 2003

KAREN LACOURCIERE
PATENT EXAMINER